

Rejection of Claims 7, 12 and 13 Under 35 U.S.C. 112, Second Paragraph (Paragraph 1 of Office Action)

Claims 7, 12 and 13 have been rejected by the Examiner under 35 U.S.C. 112, second paragraph, for the reasons set forth in paragraph 1 of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The rejection of claims 7, 12 and 13 is moot in view of the cancellation thereof.

Rejection of Claims 1 and 11 Under 35 U.S.C. 112, First Paragraph (Paragraph 2 of Office Action)

Claims 1 and 11 have been rejected by the Examiner under 35 U.S.C. 112, first paragraph, for the reasons set forth in paragraph 2 of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The rejection of claim 11 is moot in view of the cancellation thereof.

Although Applicants do not concede the propriety of the rejection with respect to claim 1, in order to expedite allowance, claim 1 has been amended to clarify the scope of the present invention. Support for the amendment to claim 1 includes the description on page 4, line 7 of the specification.

In view of the amendment to claim 1 and the cancellation of claim 11, reconsideration and withdrawal of the rejection under 35 U.S.C. 112, first paragraph, is respectfully requested.

Rejection of Claims 1-13 under 35 U.S.C. 102(b) (Paragraph 3 of Office Action)

Claims 1-13 have been rejected by the Examiner under 35 U.S.C. 102(b) as being anticipated by JP 3-72426 or Tsuchiya et al. for the reasons set forth in paragraph (3) of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Present Invention

The present invention as recited in claim 1, as amended relates to a substantially anhydrous ointment consisting essentially of acetylsalicylic acid and a base selected from the group consisting of hydrocarbon gel, vaseline and a mixture thereof without any other additive for said acetylsalicylic acid.

The Examiner maintains the position that the cited art identically discloses each element of instant claims. Applicants respectfully disagree.

Definition of the Phrase "Substantially Anhydrous"

On pages 2 and 3 of the Office Action, the Examiner indicates that the phrase "substantially anhydrous" as referred to in claim

1 implies the presence of water and does not exclude water, which according to the Examiner is a conventional solubilizing agent. Applicants respectfully disagree.

The language of claim 1 has been amended to change the phrase "solubilizing agent" to "other additive," and claim 1 should be interpreted to exclude water therefrom. Further, one of ordinary skill in the art knows that a "substantially anhydrous" state does not mean the existence of an amount of water which acts as a solubilizing agent or which dissolves aspirin in some amount (not a very small amount). Based on the understanding of one of ordinary skill in the art and based on Applicants' arguments/amendments indicating that water is excluded from the claims, the prior art rejections should be withdrawn.

**Rejection over JP 3-72426**

JP 3-72426 discloses and claims an "ointment composition containing aspirin for therapy of neuralgia comprising ointment base containing as active substance 0.5-5% by weight of aspirin and 0.5-30% by weight of aspirin solubilizing agents." Thus, contrary to the present invention, JP 3-72426 requires solubilizing agents, which are excluded from the present claims.

Further, JP 3-72426 utilizes vaseline, plastibase, etc. as the ointment base.

JP 3-72426 discloses stabilizing an aspirin ointment by the use of aspirin solubilizing agents such as diethyleneglycolmonoethyl ether, etc. Therefore, JP 3-72426 requires that it is essential to contain solubilizing agents in the ointment.

Contrary to the teachings of JP 3-72426, the present invention contains aspirin and at least one of vaseline or hydrocarbon gel and does not contain any solubilizing agent as required by JP 3-72426. Thus, the present invention is neither disclosed nor suggested by the teachings of the cited reference.

Accordingly, in view of the amendments to the claims and in view of the remarks hereinabove, the rejection of the claims over JP 3-72426 should be withdrawn by the Examiner.

Rejection Over Tsutiya et al.

The Tsutiya et al. reference discloses that the water content affects the stability of aspirin-ointment and that when polyoxyethylenehydrogenated castor oil 60 is used instead of glyceryl monostearate and when isopropanol is used instead of crotamiton as the aspirin solvent, they are effective in stabilizing the aspirin ointment.

The Tsutiya et al. reference is completely silent with respect to the use of vaseline and/or hydrocarbon gel as a stabilizing


agent for an aspirin ointment. Therefore, the Tsutiya et al. reference does not anticipate the present invention.

Accordingly, in view of the amendments to the claims and the remarks hereinabove, the rejection(s) of the claims under 35 U.S.C. 102(b) should be withdrawn by the Examiner.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANCES MADE

IN THE CLAIMS

Claims 7, 11, 12 and 13 have been cancelled.

Claim 1 has been amended as follows:

Claim 1 (Twice Amended) A substantially anhydrous ointment consisting essentially of acetylsalicylic acid and a base selected from the group consisting of hydrocarbon gel, vaseline and a mixture thereof without [any solubilizing agent] any other additive for said acetylsalicylic acid.

Claims 14 and 15 have been added.